

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bruce Tockman et al.

Title: LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF

Docket No.: 279.246US1

Filed: August 1, 2000

Examiner: George Robert Evanisk



Serial No.: 09/630,000

Due Date: October 17, 2004

Group Art Unit: 3762

Mail Stop Appeal Brief--Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

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- ☒ A return postcard.
- ☒ An Appeal Brief (25 pgs.) *including authorization to charge Deposit Account No. 19-0743 in the amount of \$340.00 to cover the Appeal Brief fee.*
- ☒ A copy of the Office Action dated 8/18/2003 (11 pgs.).
- ☒ A copy of the Final Office Action dated 3/17/2004 (11 pgs.).
- ☒ A copy of the Amendment and Reponse to Final Office Action dated 5/17/2004 (20 pgs.).
- ☒ A copy of the Advisory Action dated 7/7/2004 (6 pgs.).
- ☒ Copies of U.S. Patent Nos. 6,249,708 and 5,935,159.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

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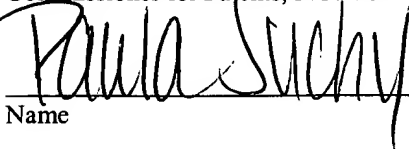
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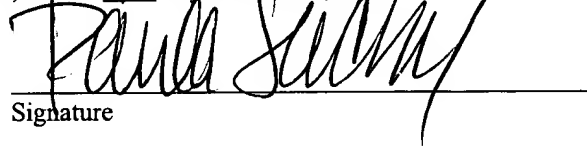
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Bruce Tockman et al.)	Examiner: George R. Evanisko
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Serial No.: 09/630,000)	Group Art Unit: 3762
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APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on August 17, 2004, from the Final Rejection of claims 16-26 and 43-46 of the above-identified application, as set forth in the Final Office Action mailed on March 17, 2004.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 01-0857 in the amount of 340.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of the pending claims.

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APPELLANTS' BRIEF ON APPEAL

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1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is Cardiac Pacemakers, Inc., 4100 Hamline Avenue North, St. Paul MN 55112.

2. RELATED APPEALS, INTERFERENCES AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences or judicial proceedings known to Appellants' Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF THE CLAIMS

Claims 1-15 are canceled. Claims 27-42 are withdrawn. Claims 16-26 and 43-46 are pending and are the subject of this Appeal (see Appendix I). Claims 16-26 and 43-46 were rejected in the Final Office Action dated March 17, 2004.

4. STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the Amendment and Response filed by Appellants on May 17, 2004. The claims listed in Appendix I reflect the claims as they currently exist.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

The invention is directed to a lead assembly having varying stiffness for assisting in retaining and/or positioning the lead assembly in a desired location of the heart, vein or artery. The lead assembly further relates to applications where an electrode is disposed in a larger vein or artery where it is otherwise difficult to position and/or maintain an electrode against the wall of the surrounding tissue.

The lead assembly includes a lead body, such as lead body 115 shown, for example, in Figure 1. Specification page 7, lines 1-3. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion therebetween. Specification page 7, lines 5-6 and page 7, lines 13-14. The lead body includes two or more coradial individually insulated

coradial conductors disposed therein, such as a first conductor and a second conductor. Specification page 8, lines 8-9 and page 12, lines 18-22. For instance, first and second conductors 140, 142 are shown in Figure 1, and first and second conductors 240, 242 are shown in Figure 9. The conductors are wound about a single axis as shown in Figures 1 and 9. See Amendment and Response dated May 17, 2004 to Final Office Action dated March 17, 2004, replacement paragraphs at page 8, line 8 and page 12, line 12.

The first conductor is comprised of a first material, and the second conductor is comprised of a second material. The first material has a different stiffness than the second material, as discussed, among other places, in the specification page 11, lines 9-20 and page 12, lines 18-25. Additionally, the lead assembly includes an electrode assembly having at least one electrode electrically coupled with at least one of the conductors, for example, electrode 120 shown in Figure 1. Specification page 8, lines 14-18.

6. ISSUES PRESENTED FOR REVIEW

- a. Whether claims 16-26 and 43-46 are patentable under 35 U.S.C. § 103 over U.S. 6,249,708 to Nelson et al?
- b. Whether claims 16-26 and 43-46 are patentable under 35 U.S.C. § 103 over U.S. 5,935,159 to Cross, Jr. et al?

7. ARGUMENT

a. The Applicable Law

Establishing a Prima Facie Case of Obviousness Under 35 U.S.C. 103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* The MPEP contains explicit direction to the Examiner that agrees with the court in *In re Fine*:

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellants' disclosure.

MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Analysis of Suggestion to Modify/Combine References under 35 U.S.C. 103

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). At the same time, however, although it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). Additionally, "the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art,

established scientific principles or legal precedent.” (Emphasis Added). *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988), M.P.E.P. § 2144.

According to *In re Sang Su Lee*, "there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the Appellants." *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002), citing *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). Furthermore, the "factual question of motivation is material to patentability, and could *not* be resolved on *subjective belief and unknown authority*." (Emphasis Added). *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). A showing of a suggestion, teaching, or motivation to combine prior teachings "must be clear and particular . . . Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *In re Dembiczak*, 175 F.2d 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

Invention as a Whole Must be Considered under 35 U.S.C. 103

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). The Examiner can only rely on references which are either in the same field as that of the invention, or if not in the same field, must be "reasonably pertinent to the particular problem with which the inventor was concerned." MPEP § 2141.01 (a) (citing *In re Oetiker*, 24 U.S.P.Q.2d 1443 at 1445). The Examiner must also recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990), reh'g denied, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). For instance, the reference must be considered as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 369 U.S. 851 (1984). Finally, the Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990), reh'g denied, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). The Examiner cannot use the Appellants's structure

as a "template" and simply select elements from the references to reconstruct the claimed invention. *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991).

All elements of the Claims must be Considered during Examination

The United States Supreme Court expressly stated and made clear that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S. Ct. 1040, 1049, 137 L.Ed.2d 146, 161, 41 U.S.P.Q.2d 1865, 1871 (1997). Each claim must be read in view of the specification of which it is a part, and in view of the other claims. *In re Marosi, Stabenow, and Schwarzmann*, 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983). The use of hindsight to modify or extend the teachings of a reference to the claimed invention is improper, and may not be used as the basis for rejection. *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002).

The Specification must describe how to make and use the Invention under 35 U.S.C. 112, First Paragraph

The standard for determining whether the specification of a reference meets the enablement requirement was provided by the United States Supreme Court in *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The Supreme Court stated the enablement requirement was not met where undue or unreasonable experimentation was needed to practice the invention. *Id.* 35 U.S.C. 112, first paragraph thus requires that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 737, 737 (Fed. Cir. 1988).

b. Discussion of the Rejections of Claims 16-26 and 43-46

i. Claims 16-20, 24, 26, 43, 45 and 46 were improperly rejected under 35 U.S.C. 103 as being unpatentable over Nelson et al. (U.S. 6,249,708), hereinafter Nelson.

Appellants respectfully submit that the rejection of claims 16-20, 24, 26, 43, 45 and 46 under 35 U.S.C. 103 is improper. Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 are respectfully requested.

(a) The Rejection of Claims 16-20, 24, 26, 43, 45 and 46 Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

The rejections of claims 16-20, 24, 26, 43, 45 and 46 fail to state a *prima facie* case of obviousness because the Final Office Action fails to identify a proper motivation to modify the reference in the manner proposed. The Final Office Action states at page 3, second paragraph, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials . . . since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead." However, despite asserting that this was "known in the art" no objective reference was provided in a fully developed rejection under 35 USC § 103 establishing such an assertion. Instead, the Final Office Action merely states at page 6, paragraph 3, "the last office action [dated August 18, 2003] provided three teachings (US patents 6253111, 4640983, 6400992) that show the use of different conductors having different stiffness." None of these references were used in a fully developed rejection under 35 USC § 103. Appellants respectfully submit the statement is thus conclusory and does not appear to be reasoned as required by *In re Fine*, and therefore does not provide a rationale to modify Nelson in the manner proposed. Furthermore, the assertion is not objective as required by *In re Lee*.

Furthermore, the Final Office Action does not state how or why Nelson would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in claims 17-20, 24, 26, 43, 45 and 46.

Further still, the Advisory Action dated July 7, 2004 reiterates the position of the

Final Office Action and fails to remedy the absence of an objective motivation to selectively modify Nelson in the manner proposed. The Advisory Action states at page 2, "it was well known in the art to provide different materials for the conductors . . . this being the modification of the primary references, since the primary references state that different conductors can be used." Appellants respectfully submit Nelson states at column 5, lines 45-47, "Preferably, each conductor 44 is a multifilar wound coil, although a unifilar wound coil a multifilament cable or any combination thereof could be used for the conductors 44." However, Nelson fails to teach or suggest individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in claims 17-20, 24, 26, 43, 45 and 46. Appellants respectfully submit Nelson does not appear to show how conductors having different materials can be used.

The Final Office Action fails to provide objective motivation to selectively modify Nelson in the manner proposed. Absent such objective motivation, the Final Office Action fails to establish a *prima facie* case of obviousness. Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 is respectfully requested.

(b) The Rejection of Claims 16-20, 24, 26, 43, 45 and 46 Fails to Establish a *Prima Facie* Case of Obviousness Because Nelson Teaches Away From the Claims.

The rejection of claims 16-20, 24, 26, 43, 45 and 46 fails because, among other reasons, Nelson teaches away from the proposed modification. Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. Nelson states at column 4, lines 40-45, "Because the catheter lead 10 is preferably constructed of a flexible medical grade silicon rubber material, the ability of the fluted channels 42 to serve as mechanisms for inserting a stiffening material . . . allows for the construction of . . . transition zones (i.e.,

longitudinal lengths of the lead having different flexibility characteristics than adjacent regions).” Moreover, Nelson states at column 9, line 66 to column 10, line 1, “a stiffening material [fills] at least a portion of at least one of the plurality of longitudinally-oriented fluted channels that is open and *without a conductor*.” (Emphasis Added).

Nelson teaches away from the proposed modification because Nelson advises using inserted stiffening material that is separate from the conductors, and that is not the conductor, as opposed to the apparatus recited in claim 16 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

Furthermore, the Advisory Action fails to rebut that Nelson teaches away from the proposed modification. The Advisory Action states at page 2, “the argument that Nelson or Cross teach away from the 103 combination because Nelson or Cross teach that the lead can be stiffened by inserting a stiffening element in the channels or are provided with a stiffening core are not persuasive since Nelson or Cross do not preclude the use of stiffening the lead with conductors.” Appellants respectfully disagree that a reference needs to preclude other avenues of performing a desired function in order to teach away from a proposed modification. Appellants submit Nelson teaches away from the proposed modification which cuts against a motivation to selectively modify Nelson in the manner proposed. Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 is respectfully requested.

(c) The Rejection of Claims 16-20, 24, 26, 43, 45 and 46 Fails to Establish a *Prima Facie* Case of Obviousness Because Nelson Does Not Teach or Suggest All Elements of the Claims and Nelson is not Enabled to Teach All Elements of the Claims.

The rejection of claims 16-20, 24, 26, 43, 45 and 46 fails because Nelson does not teach or suggest all the elements recited in claim 16 or incorporated in claims 17-20, 24,

26, 43, 45 and 46. Appellants cannot find, for example, a lead body including two or more coradial individually insulated coradial conductors disposed therein, wherein the coradial conductors are wound about a single axis, as recited in claim 16. Moreover, Appellants cannot find, the individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material. Appellants respectfully submit Nelson states at column 5, lines 3-5, “an outer insulative sheath member 46 surrounds the inner body member 30 and the conductors 44.” Appellants submit Nelson appears to consolidate insulation of each of the conductors with the outer insulative sheath member and therefore Nelson does not teach or suggest all the elements recited in claim 16 or incorporated in claims 17-20, 24, 26, 43, 45 and 46.

Further, Appellants respectfully submit Nelson appears to provide no enabling disclosure that would teach or suggest to a person skilled in the art how to make and use Appellant’s claimed invention. For example, the Advisory Action states at page 2, “the argument that Nelson or Cross teach away from the 103 combination because Nelson or Cross teach that the lead can be stiffened by inserting a stiffening element in the channels or are provided with a stiffening core are not persuasive *since Nelson or Cross do not preclude the use of stiffening the lead with conductors.*” (Emphasis Added). However, Nelson fails to provide enabling disclosure for using individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in claims 17-20, 24, 26, 43, 45 and 46. Instead, as provided above, Nelson recites “a stiffening material [filling] at least a portion of at least one of the plurality of longitudinally-oriented fluted channels that is open and *without a conductor.*” (Emphasis Added). Nelson, column 9, line 66 to column 10, line 1. Appellants respectfully submit Nelson provides no enabling disclosure to support the assertions made in the Advisory Action. Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 is respectfully requested.

(d) The Rejection of Claims 16-20, 24, 26, 43, 45 and 46 Fails to Establish a *Prima Facie* Case of Obviousness Because the Final Office Action Does Not Consider the Claims as a Whole.

The rejection of claims 16-20, 24, 26, 43, 45 and 46 fails because the rejection does not consider the claims as a whole. For example, the Final Office Action at page 3, second paragraph states, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials." The Final Office Action fails to consider, for example, that claim 16 recites the conductors are individually insulated, coradial and include a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material. Appellants respectfully submit the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established. Additionally, by failing to consider the invention as a whole, the Final Office Action uses the Appellants' disclosure as a template and performs hindsight reconstruction to selectively modify Nelson in the proposed manner. According to *In re Vaeck*, the teaching or suggestion to make the claimed device must be found in the prior art, not in the Appellants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 are respectfully requested.

ii. Claims 21-23, 25 and 44 were improperly rejected under 35 USC 103 as being unpatentable over Nelson et al. (U.S. Patent No. 6,249,708).

Appellants respectfully submit that the rejection of claims 21-23, 25 and 44 under 35 U.S.C. 103 is improper. Reconsideration and allowance of claims 21-23, 25 and 44 are respectfully requested.

(a) Claims 21-23 are patentable over Nelson because Claims 21-23, depend either directly or indirectly from patentable independent claim 16, and the Arguments Discussed Above for Claims 16-20, 24, 26, 43, 45 and 46 are Incorporated herein for Claims 21-23.

Claims 21-23 contain additional limitations to independent claim 16. Claims 21-23 depend from claim 16 and are patentable as discussed above. Reconsideration and allowance of claims 21-23 are respectfully requested.

(b) The Rejection of Claim 25 Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

The rejection of claim 25 fails to state a *prima facie* case of obviousness because the Final Office Action fails to identify a proper motivation to modify Nelson in the manner proposed. The Final Office Action states at page 4, third paragraph, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration." However, despite asserting that this was "known in the art" no objective reference was provided in a fully developed rejection under 35 USC 103 establishing such an assertion. Instead, the Final Office Action merely states at page 6, paragraph 3, "the cited prior art of US patent 5849032 shows the use of a heat setting conductor, nitinol." Appellants respectfully submit these statements are conclusory and do not appear to be reasoned as required by *In re Fine*, and therefore do not provide a rationale to modify Nelson in the manner proposed. Furthermore, the assertion is not objective as required by *In re Lee*.

Furthermore, the Final Office Action does not state how or why Nelson would be in need of an individually insulated coradial conductors formed of material having heat

setting capabilities, as recited in claim 25. Appellants cannot find any objective suggestion in Nelson to employ such structure.

Appellants also respectfully submit that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

(c) The Rejection of Claim 44 Fails to Provide a *Prima Facie* Case of Obviousness because there is No Objective Reason to Selectively Modify Nelson and because Nelson Does Not Teach All the Elements of Claim 44.

The rejection of claim 44 fails to state a *prima facie* case of obviousness because, among other reasons, the Final Office Action fails to identify a proper motivation to modify Nelson in the manner proposed. The Final Office Action states at page 3, last paragraph, "It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson . . . [so the] first conductor [is] disposed only in the second and third sections." However, despite asserting that this was an "obvious matter of design choice" no objective reference was provided establishing such an assertion. Instead, an unsupported assertion is provided. Appellants respectfully submit the statement is thus conclusory and does not appear to be reasoned as required by *In re Fine*, and therefore does not provide a rationale to modify Nelson in the manner proposed. Furthermore, the assertion in the Final Office Action at page 3, last paragraph is not objective as required by *In re Lee*.

Further, the Final Office Action does not state how or why Nelson would be in need of the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections, as recited in claim 44. Appellants cannot find any objective suggestion in Nelson to employ such structure.

Additionally, Appellants respectfully submit Nelson does not teach all the elements of claim 44. Appellants can find no disclosure, teaching or suggestion in

Nelson of, for example, the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections.

Further, the Office Action states at page 3, last paragraph, "Nelson discloses the claimed invention but does not disclose expressly . . . the first conductor being disposed only in the second and third sections." Appellants respectfully submits, claim 44 recites the first conductor is disposed only in the first and third sections.

Moreover, absent such a showing of objective support or objective reasoning, Appellants assumes the Examiner is taking Official Notice of the missing elements. Appellants respectfully submit there appears to be no evidence in the record to support taking Official Notice, and request a reference showing the missing elements. Alternatively, Appellants submit the assertions made are unsupported by the reference and are within the personal knowledge of the Examiner. Further, the Examiner has stated in the Final Office Action at page 7, last paragraph, "The Examiner has not made a 103 rejection on common knowledge in the art or 'well known' prior art." Appellants therefore submit the assertions appear to be within the personal knowledge of the Examiner. Appellants request an Examiner's affidavit supporting the unsupported assertions pursuant to 37 C.F.R. 1.104(d)(2).

Appellants also respectfully submit that claim 44 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 44.

Appellants submit that the rejection fails to establish all of the elements of claim 44, and further fails to identify an objective motivation to selectively modify the Nelson reference, each failing to establish a *prima facie* case of obviousness. Reconsideration and allowance of claim 44 are respectfully requested.

Appellants note that the Advisory Action states on page 1 that the previous response dated April 17, 2004 overcame the rejection of claim 44. The arguments above are provided for completeness of the Appeal Brief. Additionally, the arguments are provided because no formal notice of allowance was provided in the Advisory Action and Appellants are unclear regarding the status of claim 44.

iii. Claims 16-20, 24, 26, 43, 45 and 46 were improperly rejected under 35 U.S.C. 103 as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 5,935,159), hereinafter Cross.

Appellants respectfully submit that the rejection of claims 16-20, 24, 26, 43, 45 and 46 under 35 U.S.C. 103 is improper. Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 are respectfully requested.

(a) The Rejection of Claims 16-20, 24, 43, 45 and 46 Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Cross.

The rejection of claims 16-20, 24, 43, 45 and 46 fails to state a *prima facie* case of obviousness because the Final Office Action does not identify a proper motivation to modify Cross in the manner proposed. The Office Action states at page 4, last paragraph to page 5, first paragraph, "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials . . . since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead." However, despite asserting that this was "known in the art" no objective reference was provided in a fully developed rejection under 35 USC § 103 establishing such an assertion. Instead, the Final Office Action merely states at page 6, paragraph 3, "the last office action [dated August 18, 2003] provided three teachings (US patents 6253111, 4640983, 6400992) that show the use of different conductors having different stiffness." None of these references were used in a fully developed rejection under 35 USC § 103. Appellants respectfully submit the statement is thus conclusory and does not appear to be reasoned as required by *In re Fine*, and therefore does not provide a rationale to modify Cross in the manner proposed. Furthermore, the assertion is not objective as required by *In re Lee*.

Further, the Office Action does not state how or why Cross would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in dependent claims 17-20, 24, 43, 45 and 46. Appellants cannot find any objective suggestion in Cross to employ such structure and therefore the rejection of claims 16-20, 24, 43, 45 and 46 fails to provide a *prima facie* case of obviousness.

(b) The Rejection of Claims 16-20, 24, 43, 45 and 46 Fails to Establish a *Prima Facie* Case of Obviousness Because Cross Teaches Away From the Claims.

The rejection of claims 16-20, 24, 43, 45 and 46 fails because, among other reasons, Cross teaches away from the proposed modification. Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. Appellants submit Cross states at column 4, lines 40-45, “the core 102a takes the form of multiple sections 150, 152 and 154 which are structurally identical to one another, but are extruded of differing materials. For example, if a change in flexibility is desired along the length of the lead, core members fabricated of polyurethanes of differing hardness may be employed.”

Cross teaches away from the proposed modification because Cross advises using extruded sections comprised of differing material that are separate from the conductors, and that are not the conductors, as opposed to the apparatus recited in claim 16 and incorporated in claims 17-20, 24, 43, 45 and 46 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

Furthermore, the Advisory Action fails to rebut that Cross teaches away from the proposed modification. The Advisory Action states at page 2, “the argument that Nelson

or Cross teach away from the 103 combination because Nelson or Cross teach that the lead can be stiffened by inserting a stiffening element in the channels or are provided with a stiffening core are not persuasive since Nelson or Cross do not preclude the use of stiffening the lead with conductors.” Appellants respectfully disagree that a reference needs to preclude other avenues of performing a desired function in order to teach away from a proposed modification. Appellants submit Cross teaches away from the proposed modification which cuts against a motivation to selectively modify Cross in the manner proposed. Therefore the rejection of claims 16-20, 24, 43, 45 and 46 fails to provide a *prima facie* case of obviousness.

(c) The Rejection of Claims 16-20, 24, 43, 45 and 46 Fails to Establish a *Prima Facie* Case of Obviousness Because the Final Office Action Does Not Consider the Claims as a Whole.

The rejection of claims 16-20, 24, 43, 45 and 46 fails because the rejection does not consider the claims as a whole. For example, the Office Action at page 4, last paragraph to page 5, first paragraph states, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials.” In contrast, for example, claim 24 recites that the apparatus includes, *in combination with all of the elements of claim 16*, a third coradial conductor and a fourth coradial conductor, the first, second, third, and fourth conductors are disposed at the proximal end of the lead body, and the first and second conductors are disposed at the distal end of the lead body. The Final Office Action fails to address and fails to show teaching or suggestion for this new combination, along with other combinations provided in claims 17-20, 43, 45 and 46. Appellants respectfully submit the Final Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established. Additionally, by failing to consider the invention as a whole, the Final Office Action uses

the Appellants' disclosure as a template and performs hindsight reconstruction to selectively modify Cross in the proposed manner. According to *In re Vaeck*, the teaching or suggestion to make the claimed device must be found in the prior art, not in the Appellants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Reconsideration and allowance of claims 16-20, 24, 43, 45 and 46 are respectfully requested.

Additionally, Appellants respectfully traverse the statement in the Final Office Action at page 5, first paragraph, "the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section." Appellants are unaware of such a claimed limitation. Appellants respectfully request clarification or withdrawal of the statement.

Clarification of the rejection of claims 16-20, 24, 43, 45 and 46 is respectfully requested. Reconsideration and allowance of claims 16-20, 24, 43, 45 and 46 are respectfully requested.

iv. Claims 21-23, 25 and 26 were improperly rejected under 35 USC 103 as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 6,249,708).

Appellants respectfully submit that the rejection of claims 21-23, 25 and 26 under 35 U.S.C. 103 is improper. Reconsideration and allowance of claims 21-23, 25 and 26 are respectfully requested.

(a) Claims 21-23 and 26 are patentable over Cross because Claims 21-23 and 26 depend either directly or indirectly from patentable independent claim 16, and the Arguments Discussed Above for Claims 16-20, 24, 43, 45 and 46 are Incorporated herein for Claims 21-23 and 26.

Claims 21-23 and 26 contain additional limitations to independent claim 16. Claims 21-23 and 26 depend from claim 16 and are patentable as discussed above. Reconsideration and allowance of claims 21-23 and 26 are respectfully requested.

(b) The Rejection of Claim 25 Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Cross.

The rejection of claim 25 fails to provide a *prima facie* case of obviousness because the Final Office Action does not identify a proper motivation to modify Cross in the manner proposed. The Office Action states at page 6, third paragraph, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities . . . since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration." However, despite asserting that this was "known in the art" no objective reference was provided in a fully developed rejection under 35 USC 103 establishing such an assertion. Instead, the Final Office Action merely states at page 6, paragraph 3, "the cited prior art of US patent 5849032 shows the use of a heat setting conductor, nitinol." Appellants respectfully submit theses statements are conclusory and do not appear to be reasoned as required by *In re Fine*, and therefore do not provide a rationale to modify Nelson in the manner proposed. Furthermore, the assertion is not objective as required by *In re Lee*.

Furthermore, the Office Action does not state how or why Cross would be in need of individually insulated coradial conductors formed of material having heat setting capabilities, as recited in claim 25. Appellants cannot find any objective suggestion in Cross to employ such structure and therefore the rejection of claim 25 fails to provide a *prima facie* case of obviousness.

Appellants also respectfully submit that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

8. SUMMARY AND REMARKS CONCERNING THE RESPONSE TO ARGUMENTS

The Final Office Action fails to establish a legally sufficient case of obviousness and Appellants traverse on several grounds as described in detail above. The Nelson and Cross references are inapplicable on several grounds. Appellants note that the Final Office Action selectively modifies the Nelson and Cross references without the legally required objective reasoning. Appellants respectfully submit the Advisory Action fails to remedy the deficiency of motivation to selectively modify Nelson or Cross. Furthermore, Appellants respectfully submit the Final Office Action does not consider the claims as a whole.

In light of the above, Appellants submit that when properly considered as a whole, and when the actual claim language is examined without hindsight reconstruction, the pending claims are patentable over the cited art. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

Bruce Tockman et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER &
KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

Date

10/15/04

By

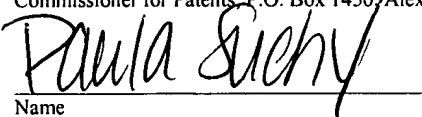


Thomas C. Obermark

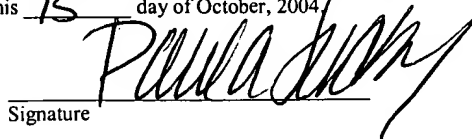
Reg. No. 55,506

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15 day of October, 2004.

Name



Signature



APPENDIX I

The Claims on Appeal

16. An apparatus comprising:

a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween; the lead body including two or more coradial individually insulated coradial conductors disposed therein, wherein the coradial conductors are wound about a single axis;

the individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material; and

an electrode assembly including at least one electrode electrically coupled with at least one of the conductors.

17. The apparatus as recited in claim 16, wherein at least one coradial conductor traverses from the proximal end to the distal end, and at least one other coradial conductor traverses along only a portion of the lead body.

18. The apparatus as recited in claim 17, wherein the at least one other coradial conductor electrically and mechanically terminates at the electrode assembly.

19. The apparatus as recited in claim 16, wherein one or more coradial conductors includes two or more filars.

20. The apparatus as recited in claim 16, wherein the first material and the second material have different electrical properties.

21. The apparatus as recited in claim 16, wherein the first material comprises MP35N.

22. The apparatus as recited in claim 21, wherein the second material comprises Pt/Ta.

23. The apparatus as recited in claim 22, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first coradial conductor is disposed only in the second and third sections.

24. The apparatus as recited in claim 16, wherein the individually insulated coradial conductors further include a third coradial conductor and a fourth coradial conductor, the first, second, third, and fourth conductors disposed at the proximal end of the lead body, and the first and second conductors disposed at the distal end of the lead body.

25. The apparatus as recited in claim 16, wherein at least one of the individually insulated coradial conductors is formed of material having heat setting capabilities.

26. The apparatus as recited in claim 16, wherein the individually insulated coradial conductors and the lead body have a two or three dimensional bias.

43. The apparatus as recited in claim 16, wherein the coradial conductors form a single lumen within the lead body.

44. The apparatus recited in claim 16, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections.

45. The apparatus recited in claim 16, wherein the two or more coradial conductors are concentric with the lead body.

46. The apparatus recited in claim 16, wherein the two or more coradial conductors lie adjacent to the outer surface of the lead body.

APPEAL BRIEF

Serial Number: 09/630,000

Filing Date: August 1, 2000

Title: LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREFOR

Page 24

Dkt: 279.246US1

APPENDIX II

Office Actions and Amendments

Office Action dated 8/18/2003

Final Office Action dated 3/17/2004

Amendment and Response to Final Office Action dated 5/17/2004

Advisory Action dated 7/07/2004

APPEAL BRIEF

Serial Number: 09/630,000

Filing Date: August 1, 2000

Title: LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREFOR

Page 25

Dkt: 279.246US1

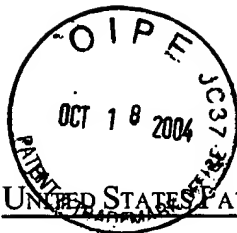
APPENDIX III

Art of Record

I. Art of Record

U.S. 6,249,708 entered in the Office Action dated August 18, 2003.

U.S. 5,935,159 entered in the Office Action dated August 18, 2003.



T_SLW01838

UNITED STATES PATENT AND TRADEMARK OFFICE

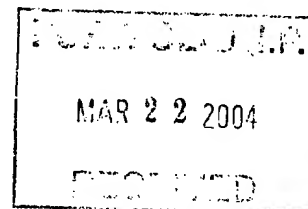
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,000	08/01/2000	Bruce Tockman	279.246US1	8111
21186	7590	03/17/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/17/2004



Please find below and/or attached an Office communication concerning this application or proceeding.



FOAR

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>09/630,000</p>	<p>Applicant(s)</p> <p>TOCKMAN ET AL.</p>	
	<p>Examiner</p> <p>George R Evanisko</p>	<p>Art Unit</p> <p>3762</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-46 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 5.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "coradial" is not used in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20, 24, 26, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelsson et al (6249708).

Nelson discloses the claimed invention and the use of different types of conductors, (multifilar, unifilar, any combination of the two, DBS) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, it is inherent that the different conductors will have different electrical properties.

Claims 21-23, 25, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.

Nelson discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the first conductor disposed only in the second and third sections (claims 23 and 44). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson with the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections, because Applicant has not disclosed that the first material being

MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors and the termination of the first conductor at its respective electrode and connector as taught by Nelson in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead and provide the needed length of the first conductor to provide electrical therapy or sensing to the electrode.

Therefore, it would have been an obvious matter of design choice to modify Nelson to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration.

Claims 16-20, 24, 43, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al (5935159).

Cross discloses the claimed invention and the use of different types of conductors, (stranded, coiled, having different diameters) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors

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being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section. Also, it is inherent that the different conductors will have different electrical properties.

Claims 21-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr et al.

Cross discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the lead having a two or three dimensional bias. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Cross with the first material being MP35N and the second material being Pt/TA, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors as taught by Cross in view of one having ordinary skill in the art, because it would provide a lead

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having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead.

Therefore, it would have been an obvious matter of design choice to modify Cross to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities and the lead having a two or three dimensional bias since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration and since it was known in the art that leads are provided with a two or three dimensional bias to allow the lead to be easily located in a particular part of the body and allow the lead to remain in that location.

Response to Arguments

Applicant's arguments filed 12/22/03 have been fully considered but they are not persuasive. The request for prior art that shows it would be obvious to use conductors of different materials having varying stiffness and electrical properties has previously been met. The last office action provided three teachings (US patents 6253111, 4640983, and 6400992) that show the use of different conductors having different stiffness/properties used in medical leads. In addition, the cited prior art of US patent 5849032 shows the use of a heat setting conductor, nitinol. In addition, the examiner has provided patent 5052407. The argument that the examiner has not stated how the references would be in need of the obvious modifications given in the 103 rejections (that the rejections lack some suggestion of the desirability of doing what the inventor has done) is not persuasive since in each 103 rejection the examiner has

provided the suggestion for the modification. As an example, in the first 103 rejection given above, the examiner stated that it is known to provide leads with different conductors made of different materials and stiffness "to provide different and required impedances, different current carrying capabilities, and/or different flexibility/stiffness to the lead". The argument that the references do not show the conductors forming a lumen is not persuasive. The conductors do form a lumen, but the lumen is filled with different materials of the lead body. The claim does not state that the lumen is empty.

The argument that the examiner needs to provide references for the 103 rejections based on criticality and that the examiner is taking official notice is not persuasive. The argument that the examiner has a burden to develop a prima facie case of obviousness by providing references which include each limitation of the claims is not persuasive. According to MPEP 2144, sources of rationale supporting a rejection under 35 USC 103 may be in a reference, or reasoned from common knowledge in the art, scientific principles, art recognized equivalents, or legal precedent.

The statement that the applicant requests a reference according to MPEP 2144.03 to support the alleged case of obviousness is not valid. The examiner only needs to provide a reference if there is a reliance on common knowledge in the art or "well known" prior art. The examiner has not made a 103 rejection on common knowledge in the art or "well known" prior art. The examiner is not stating that the 103 rejections are due to common knowledge but stating that the specification has not provided any reasoning or criticality for the claimed elements and lacking such, the examiner does not find patentable subject matter in those limitations. The systems of the prior art operate on basically the same principle and in the same manner as the

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applicant's device. Those limitations which applicant relies on provide no novel or unexpected results and use of such limitations in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill in the art. (see *In re Kuhle*, 188 USPQ 7 and MPEP 2144.04)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

3/12/04

GRE
March 12, 2004

Notice of References Cited	Application/Control No. 09/630,000		Applicant(s)/Patent Under Reexamination TOCKMAN ET AL.	
	Examiner George R Evanisko		Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,052,407	10-1991	Hauser et al.	607/125
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



EXPEDITED PROCEDURE – EXAMINING GROUP 3762

S/N 09/630000

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bruce Tockman et al.	Examiner:	George Robert Evanisko
Serial No.:	09/630,000	Group Art Unit:	3762
Filed:	August 1, 2000	Docket No.:	279.246US1
Title:	LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF		

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.116

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



This responds to the Final Office Action dated March 17, 2004.

IN THE SPECIFICATION

Please replace the paragraph beginning at page 8, line 8 with the following replacement paragraph:

A first conductor 140 and a second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. A third conductor 144 and a fourth conductor 146 extend from the proximal end 104 to the second intermediate portion 110. As a result, the first and second conductors 140, 142 are disposed in the first, second, and third sections 180, 182, 184 of the lead 100. The third and fourth conductors 144, 146 are disposed in the first and second sections, 180, 182. Optionally, an electrode 120 is disposed between the first and second sections 180, 182, and/or the electrode 120 is disposed between the second and third sections 182, 184. One or more of the first, second, third, or fourth conductors 140, 142, 144, 146 optionally electrically terminate at the electrode 120. As shown in Figure 1, the first, second, third, and fourth conductors 140, 142, 144, 146 are coradial, in one option. For instance, the first, second, third, and fourth conductors 240, 242, 244, 246 extend around a single axis (e.g. the longitudinal axis of the lead 100) and have substantially similar radii with respect to the single axis.

Please replace the paragraph beginning at page 12, line 18 with the following replacement paragraph:

As discussed above, the lead 100 includes a first conductor and a second conductor, which, in one embodiment, are formed of two different materials. Figure 9 illustrates one example of a winding configuration for a portion of a conductor assembly 200 for use in the lead 100 which includes a first conductor 240 and a second conductor 242 each formed of a different material. Optionally, a third 244 and a fourth 246 conductor are included. For instance, the first conductor 240 and the third conductor 244 are formed of MP35N and the second 242 and the fourth 246 conductor are formed of Pt/Ta. As shown in Figure 9, in another option, the first, second, third, and fourth conductors 240, 242, 244, 246 are coradial. For example, the conductors 240, 242, 244, 246 are wound around a single axis (e.g. the longitudinal axis of the

lead 100) and have substantially similar radii with respect to the single axis. The first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are each wound together, and transition to the second conductor 242 and the fourth conductor 246, as shown in Figure 9, and as further described below. It should be noted that the conductor assembly 200 can be used in any of the above or below described embodiments, and that other winding configurations are possible.

Please replace the paragraph beginning at page 13, line 3 with the following replacement paragraph:

Figure 10 illustrates another example of how to form the conductor assembly 200. The conductor assembly 200 is wound, for example, using a mandrel. The conductor assembly 200 is wound with four conductors, including the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246, which are each wound from a proximal end 204 to a distal end 202 of the conductor assembly 200. As shown in Figure 10, in one option, the first, second, third, and fourth conductors 240, 242, 244, 246 are coradial, as described above. In one embodiment, two or more different materials are used for forming the conductor assembly 200. In another embodiment, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are electrically terminated at various locations 250 along the conductor assembly 200. Optionally, during the winding of the coil assembly 200, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 is dropped out of the winding, for instance, at a location of an electrode.

IN THE CLAIMS

A set of claims is provided below for the convenience of the Examiner.

1-15. (Canceled)

16. (Previously Presented) An apparatus comprising:

a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween, the lead body including two or more coradial individually insulated coradial conductors disposed therein, wherein the coradial conductors are wound about a single axis;

the individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material; and

an electrode assembly including at least one electrode electrically coupled with at least one of the conductors.

17. (Previously Presented) The apparatus as recited in claim 16, wherein at least one coradial conductor traverses from the proximal end to the distal end, and at least one other coradial conductor traverses along only a portion of the lead body.

18. (Previously Presented) The apparatus as recited in claim 17, wherein the at least one other coradial conductor electrically and mechanically terminates at the electrode assembly.

19. (Previously Presented) The apparatus as recited in claim 16, wherein one or more coradial conductors includes two or more filars.

20. (Original) The apparatus as recited in claim 16, wherein the first material and the second material have different electrical properties.

21. (Original) The apparatus as recited in claim 16, wherein the first material comprises MP35N.

22. (Original) The apparatus as recited in claim 21, wherein the second material comprises Pt/Ta.

23. (Previously Presented) The apparatus as recited in claim 22, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first coradial conductor is disposed only in the second and third sections.

24. (Previously Presented) The apparatus as recited in claim 16, wherein the individually insulated coradial conductors further include a third coradial conductor and a fourth coradial conductor, the first, second, third, and fourth conductors disposed at the proximal end of the lead body, and the first and second conductors disposed at the distal end of the lead body.

25. (Previously Presented) The apparatus as recited in claim 16, wherein at least one of the individually insulated coradial conductors is formed of material having heat setting capabilities.

26. (Previously Presented) The apparatus as recited in claim 16, wherein the individually insulated coradial conductors and the lead body have a two or three dimensional bias.

27. (Withdrawn) An apparatus comprising:

a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween, the lead body including two or more individually insulated coradial conductors disposed therein;

the insulated conductors including a first conductor and a second conductor, the first conductor traversing along less than an entire length of the lead body, the first conductor extending from the distal end of the lead body to the intermediate portion;

the second conductor traversing from the proximal end to the distal end of the lead body;

at least the first conductor is comprised of a first material, at least the second conductor is comprised of a second material, the first material having a different stiffness than the second material;

the lead body having four conductors disposed at the proximal end of the lead body, and two conductors disposed at the distal end of the lead body;
and

an electrode assembly including at least one electrode electrically coupled with at least one conductor, the first conductor electrically and/or mechanically terminating at the electrode assembly.

28. (Withdrawn) A method of varying the stiffness of a coiled conductor assembly, the method comprising:

winding a plurality of conductors to form the coiled conductor assembly
pulling at least one loop of a first conductor away from the coiled conductor assembly.

29. (Withdrawn) The method as recited in claim 28, further comprising crimping the at least one loop.

30. (Withdrawn) The method as recited in claim 29, further comprising electrically coupling the first conductor to an electrode.

31. (Withdrawn) The method as recited in claim 30, further comprising electrically terminating the first conductor at the electrode.

32. (Withdrawn) The method as recited in claim 28, further comprising spinning a mandrel and forming the coiled conductor assembly therein, and pulling the loop includes stopping the mandrel.

33. (Withdrawn) The method as recited in claim 28, further comprising pulling one or more second loops of a second conductor.

34. (Withdrawn) The method as recited in claim 28, further comprising pulling one or more second loops of a second conductor having a different material than the first conductor.

35. (Withdrawn) The method as recited in claim 33, wherein pulling one or more second loops is performed directly adjacent to the first loop.

36. (Withdrawn) The method as recited in claim 33, further comprising pulling one or more third loops of a third conductor.

37. (Withdrawn) The method as recited in claim 36, further comprising pulling one or more third loops of a fourth conductor.

38. (Withdrawn) A method of modifying a stiffness of a lead extending from a proximal end to a distal end, where the lead includes two or more conductors therein, the method comprising:

forming insulation on the two or more conductors; and

winding the two or more conductors and dropping out one or more conductors at an intermediate portion of the lead.

39. (Withdrawn) The method as recited in claim 38, wherein winding the two or more conductors includes winding two or more conductors each having a different material.

40. (Withdrawn) The method as recited in claim 38, further comprising pulling a loop of at least one conductor during the winding.

41. (Withdrawn) The method as recited in claim 40, further comprising crimping and swaging the loop of conductor.

42. (Withdrawn) The method as recited in claim 41, further comprising electrically coupling the conductor with an electrode of the lead.

43. (Previously Presented) The apparatus as recited in claim 16, wherein the coradial conductors form a single lumen within the lead body.
44. (Previously Presented) The apparatus recited in claim 16, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections.
45. (Previously Presented) The apparatus recited in claim 16, wherein the two or more coradial conductors are concentric with the lead body.
46. (Previously Presented) The apparatus recited in claim 16, wherein the two or more coradial conductors lie adjacent to the outer surface of the lead body.

REMARKS

This responds to the Final Office Action dated March 17, 2004.

No claims are amended, canceled or are added; as a result, claims 16-46 are now pending in this application.

Objection to the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. Applicant has amended the specification. No new matter is introduced by the amendments. Support for the amendments is found, for example, in Figures 1 and 9-14.

Withdrawal of the objection to the specification is respectfully requested.

§103 Rejection of the Claims

Claims 16-20, 24, 26, 43, 45 and 46 were rejected under 35 USC § 103(a) as being unpatentable over Nelson et al. (U.S. Patent No. 6,249,708), hereinafter Nelson.

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

Applicant respectfully traverses the rejections. The rejections of claims 16-20, 24, 26, 43, 45 and 46 fail, among other reasons, because Nelson does not identify a proper motivation to modify the reference in the manner proposed. According to M.P.E.P. § 2143.01, the mere fact that a reference *can* be modified does not render the resultant modification obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of modification. Moreover, according to M.P.E.P. § 2144, “the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art, established scientific principles or legal precedent.” (emphasis added). The Office Action states at page 3, second paragraph, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials . . .

since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead.” Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Nelson would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in claims 17-20, 24, 26, 43, 45 and 46. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

2. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because Nelson Teaches Away From the Claims.

Applicant traverses the rejections of claims 16-20, 24, 26, 43, 45 and 46 because, among other reasons, Nelson teaches away from the proposed modification. According to M.P.E.P. § 2143.03, “Prior art must be considered in its entirety, including disclosures that teach away from the claims.” Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). Nelson states at column 4, lines 40-45, “Because the catheter lead 10 is preferably constructed of a flexible medical grade silicon rubber material, the ability of the fluted channels 42 to serve as mechanisms for inserting a stiffening material . . . allows for the construction of . . . transition zones (i.e., longitudinal lengths of the lead having different

flexibility characteristics than adjacent regions).” Moreover, Nelson states at column 9, line 66 to column 10, line 1, “a stiffening material [fills] at least a portion of at least one of the plurality of longitudinally-oriented fluted channels that is open and without a conductor.”

Nelson teaches away from the proposed modification because Nelson advises using inserted stiffening material separate from the conductors as opposed to the apparatus recited in claim 16 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

3. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because the Office Action Does Not Consider the Claims as a Whole.

The rejections of claims 16-20, 24, 26, 43, 45 and 46 fail because the rejections do not consider the claims as a whole. Pursuant to M.P.E.P. § 2141.02, “In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences *themselves* would have been obvious, but whether the claimed inventions *as a whole* would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). For example, the Office Action at page 3, second paragraph states, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials.” Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejections focus upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established. Additionally, by failing to consider the invention as a whole, the Office Action uses hindsight reconstruction. The teaching or suggestion to make the claimed device must be found in the prior art, not in the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 are respectfully requested.

Claims 21-23, 25 and 44 were rejected under 35 USC § 103(a) as being unpatentable over Nelson et al. (U.S. Patent No. 6,249,708).

Claims 21-23

Applicant respectfully submits that claims 21-23 are patentable as dependent claims of patentable base claim 16; and the discussion for claim 16 above is repeated in support of claims 21-23.

Reconsideration and allowance of claims 21-23 are respectfully requested.

Claim 25

Applicant respectfully traverses the rejection. The rejection of claim 25 fails, among other reasons, because a proper motivation to modify Nelson in the manner proposed has not been identified. The Office Action states at page 4, third paragraph, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration." Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Nelson would be in need of an individually insulated coradial conductors formed of material having heat setting capabilities, as recited in claim 25. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

Applicant also respectfully submits that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

Claim 44

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

Applicant respectfully traverses the rejection. The rejection of claim 44 fails, among other reasons, because Nelson does not identify a proper motivation to modify the reference in the manner proposed. Applicant is unaware of a requirement for showing an advantage, use for a particular purpose, or solution of a stated problem. Office Action, page 4, first paragraph. Rather, pursuant to M.P.E.P. § 706.02(j), “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” See also *In Re San Su Lee*, 277 F.3d 1338 (CAFC 2002). Applicant respectfully submits the statement in the Office Action at page 3, last paragraph, “It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson . . . [so the] first conductor [is] disposed only in the second and third sections” is a conclusory statement that does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Further, the Office Action does not state how Nelson would be in need of the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections, as recited in claim 44. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

2. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because Nelson Does Not Teach All the Elements of Claim 44.

Applicant respectfully submits Nelson does not teach all the elements of claim 44, as required by M.P.E.P. § 2143.03. Applicant can find no disclosure, teaching or suggestion in Nelson of, for example, the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections. Further, the Office Action states at page 3, last paragraph, “Nelson discloses the claimed invention but does not disclose expressly . . . the first conductor being disposed only in the second and third sections.” Applicant respectfully submits, claim 44 recites the first conductor is disposed only in the first and third sections. Pursuant to M.P.E.P. § 2143.03, Applicant respectfully requests the Examiner show in Nelson where teaching or suggestion of the missing element is found.

Moreover, absent such a showing of objective support or objective reasoning, Applicant assumes the Examiner is taking Official Notice of the missing elements. Applicant respectfully submits there appears to be no evidence in the record to support taking Official Notice, and pursuant to M.P.E.P. § 2144.03, requests a reference showing the missing elements. Alternatively, Applicant submits the assertions made are unsupported by the reference and are within the personal knowledge of the Examiner. Further, the Examiner has stated in the Office Action at page 7, last paragraph, “The Examiner has not made a 103 rejection on common knowledge in the art or ‘well known’ prior art.” Applicant therefore submits the assertions appear to be within the personal knowledge of the Examiner. Applicant requests an Examiner’s affidavit supporting the unsupported assertions pursuant to 37 C.F.R. 1.104(d)(2) and M.P.E.P. § 2144.03.

Reconsideration and allowance of claim 44 are respectfully requested.

Claims 16-20, 24, 43, 45 and 46 were rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 5,935,159), hereinafter Cross.

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Cross.

Applicant respectfully traverses the rejections. The rejections of claims 16-20, 24, 43, 45 and 46 fail, among other reasons, because Cross does not identify a proper motivation to modify the reference in the manner proposed. Pursuant to M.P.E.P. § 706.02(j), “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” See also *In Re San Su Lee*, 277 F.3d 1338 (CAFC 2002). Applicant respectfully submits that the evidence of record does not appear to identify an objective source for the motivation to modify Cross in the manner proposed. The Office Action states at page 4, last paragraph to page 5, first paragraph, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials . . . since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead.” Applicant respectfully submits the statement in the Office Action is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144.

Further, the Office Action does not state how Cross would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in dependent claims 17-20, 24, 43, 45 and 46. Applicant cannot find any objective suggestion in Cross to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Cross in the manner proposed.

2. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because Cross Teaches Away From the Claims.

The rejections of claims 16-20, 24, 43, 45 and 46 fail because, among other reasons, Cross appears to teach away from the proposed modification. Applicant submits Cross states at column 4, lines 40-45, “the core 102a takes the form of multiple sections 150, 152 and 154 which are structurally identical to one another, but are extruded of differing materials. For example, if a change in flexibility is desired along the length of the lead, core members fabricated of polyurethanes of differing hardness may be employed.” Cross teaches away from the proposed modification because Cross advises using extruded sections comprised of differing materials as opposed to the apparatus recited in claim 16 and incorporated in claims 17-20, 24, 43, 45 and 46 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

Additionally, Applicant respectfully traverses the statement in the Office Action at page 5, first paragraph, “the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section.” Applicant is unaware of such a claimed limitation. Applicant respectfully requests clarification or withdrawal of the statement.

3. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because the Office Action Does Not Consider the Claims as a Whole.

The rejections of claims 16-20, 24, 43, 45 and 46 fail because the rejections do not consider the claims as a whole. M.P.E.P. § 2141.02. For example, the Office Action at page 4, last paragraph to page 5, first paragraph states, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials.” Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejections focus upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been

established. Additionally, by failing to consider the invention as a whole, the Office Action uses hindsight reconstruction. The teaching or suggestion to make the claimed device must be found in the prior art, not in the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

Clarification of the rejections of claims 16-20, 24, 43, 45 and 46 are respectfully requested. Reconsideration and allowance of claims 16-20, 24, 43, 45 and 46 are respectfully requested.

Claims 21-23, 25 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 5,935,159).

Claims 21-23 and 26

Applicant respectfully submits that claims 21-23 and 26 are patentable as dependent claims of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claims 21-23 and 26.

Reconsideration and allowance of claims 21-23 and 26 are respectfully requested.

Claim 25

Applicant respectfully traverses the rejection. The rejection of claim 25 fails, among other reasons, because a proper motivation to modify Cross in the manner proposed has not been identified. The Office Action states at page 6, third paragraph, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities . . . since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration." Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Cross would be in need of an individually insulated coradial conductors formed of material having heat setting capabilities, as

recited in claim 25. Applicant cannot find any objective suggestion in Cross to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Cross in the manner proposed or withdraw the rejection.

Applicant also respectfully submits that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

Information Disclosure Statement

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Information Disclosure Statement filed on July 10, 2001, a Supplemental Information Disclosure Statement filed on May 7, 2002 and a Supplemental Information Disclosure Statement filed on July 13, 2001 marked as being considered and initialed by the Examiner, be returned with the next official communication.

Response to Arguments

Applicant is unclear as to the applicability of U.S. Patent Nos. 6,253,111, 4,640,983, 6,400,992, 5,849,032 and 5,052,407 to claims 16-46. The Office Action does not appear to use the references in a fully developed rejection according to M.P.E.P. § 707.07(g). Applicant respectfully traverses the statement in the Office Action at page 6, last paragraph, "The request for prior art that shows it would be obvious to use conductors of different materials having varying stiffness . . . has previously been met." Pursuant to M.P.E.P. § 707.07(g), "The Examiner should reject each claim on all valid grounds available . . . Where a major technical rejection is proper, it should be stated with a *full development* of reasons rather than by mere conclusion." (emphasis added). Applicant respectfully submits the Office Action statement at page 6, last paragraph, "The last Office Action provided three teachings . . . that show the use of different conductors having different stiffness," is conclusory and not fully developed. Pursuant to M.P.E.P. § 707.07(g), Applicant respectfully requests the Examiner provide a fully developed rejection or withdraw this line of argument. Moreover, pursuant to M.P.E.P. § 707.07(g),

Applicant respectfully requests the Examiner provide a fully developed rejection with U.S. Patent Nos. 5,849,032 and 5,052,407 (See Office Action, page 6, last paragraph) or withdraw this line of argument.

Applicant respectfully traverses the statements in the Office Action at page 7, last paragraph to page 8, first paragraph, “the specification has not provided any reasoning or criticality-for the claimed elements and lacking such, the Examiner does not find patentable subject matter in those limitations. The systems of the prior art operate on basically the same principle and in the same manner as the Applicant’s device. Those limitations which Applicant relies on provide no novel or unexpected results and use of such limitations in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill in the art.” Applicant is unaware of such standards for patentability and requests the Examiner show where such a standard is used to determine patentability.

Further, according to M.P.E.P. § 2144.04, “The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness. The prior art *must* provide a motivation or reason for the worker in the art, without the benefit of the [Applicant’s] specification, to make the necessary changes in the reference device.” (emphasis added) *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). The Office Action lacks such motivation or reason. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify the applied references in the manner proposed.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

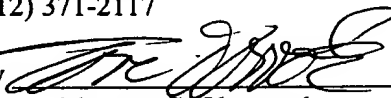
Respectfully submitted,

BRUCE TOCKMAN ET AL.

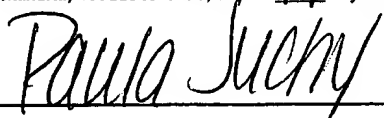
By their Representatives,


SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 371-2117

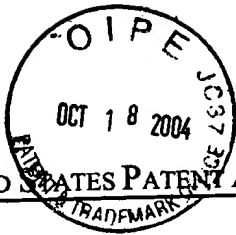
Date 5/17/04

By 
Thomas C. Obermark
Reg. No. 55,506

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of May, 2004.


Name


Signature



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3-17-04
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,000	08/01/2000	Bruce Tockman	279,246US1	8111

EXAMINER	
EVANISKO, GEORGE ROBERT	

ART UNIT	PAPER NUMBER
3762	

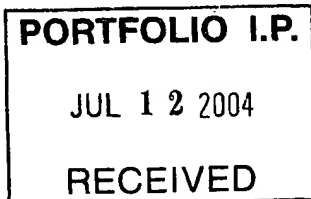
21186 7590 07/07/2004
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

DATE MAILED: 07/07/2004

Q F.R. 4th Mo - July 17, 2004
F.R. 6th Mo - Sept. 17, 2004



Please find below and/or attached an Office communication concerning this application or proceeding.



Advisory Action	Application No. 09/630,000	Applicant(s) TCKMAN ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): 103 rejection of claim 44.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: IDSs attached

George R Evanisko
Primary Examiner
Art Unit: 3762

Continuation of 5. does NOT place the application in condition for allowance because: the arguments are not persuasive. The arguments that there are no objective reasons to selectively modify Nelson and Cross and that the Examiner has not identified an objective source for the motivation of Nelson and Cross are not persuasive. First, it must be realized that a 103 rejection is an admission that the prior art does not teach every element in the claim and therefore a combination of references or a reliance on common knowledge in the art or legal precedent is necessary to provide the missing limitation(s). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Nelson and Cross do not teach the first and second conductors being different materials, with the first material having a different stiffness than the second material. But Nelson and Cross do teach that different conductors can be used in their leads. It was stated that it was well known in the art to provide different materials for the conductors, with the first material having a different stiffness than the second material (this being the modification of the primary references, since the primary references state that different conductors can be used and since both the primary and the three secondary references, provided to show obviousness and show well known in the art, are medical leads and use different conductors). The motivation to combine being that the different materials and stiffnesses provide "different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead". Therefore, the 103 rejection is proper. Also, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In addition, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In addition, the argument that Nelson or Cross teach away from the 103 combination because Nelson or Cross teach that the lead can be stiffened by inserting a stiffening element in the channels or are provided with a stiffening core are not persuasive since Nelson or Cross do not preclude the use of stiffening the lead with conductors. Nelson and Cross teach a way to stiffen the lead, but do not state that this is the only way that it can be stiffened. Numerous ways are possible to stiffen the lead, from using a stiffening element, to a stylet, conductors, and/or different lead materials, etc. Finally, sources for rationale supporting a rejection under 103 can be in a reference, or reasoned from common knowledge in the art, scientific principles, art-recognized equivalents, or legal precedent (MPEP 2144) and the examiner has previously provided references to show the teachings for the 103 rejections of being common knowledge in the art.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
 (Use as many sheets as necessary)

Complete if Known	
Application Number	09/630000
Filing Date	August 1, 2000
First Named Inventor	Tockman, Bruce
Group Art Unit	3762
Examiner Name	Jastrzab, Jeffrey

Sheet 1 of 1

Attorney Docket No: 00279.246US1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
JPL	US-2002/00494485	04/25/2002	Smits, K F.A.	607	122	09/06/2001

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
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OTHER DOCUMENTS – NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
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EXAMINER

DATE CONSIDERED

6/25/4

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 909. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant to place a check mark here if English language Translation is attached

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
 (Use as many sheets as necessary)

Complete if Known

Applicati n Number 09/630,000
 Filing Date August 1, 2000
 First Named Inventor Tockman, Bruce
 Group Art Unit 3762
 Examiner Name Khan, Omar

Attorney Docket No: 00279.246US1

Sheet 1 of 1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date if Appropriate
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FOREIGN PATENT DOCUMENTS

Examiner Initial *	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
OK	DE-20010369	09/21/2000				

OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS¹

Examiner Initial *	Cite No *	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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EXAMINER

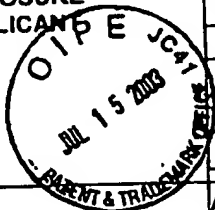
DATE CONSIDERED

2/1/03

Substitute Disclosure Statement Form (PTO-1449)

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**INFORMATION DISCLOSURE
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Approved for use through 10/31/2002. OMB 0551-0031
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Complete if Known

Application Number	09/630000
Filing Date	August 1, 2000
First Named Inventor	Tockman, Bruce
Group Art Unit	3762
Examiner Name	Khan, Omar

Attorney Docket No: 279.246US1

Sheet 1 of 1

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date (if Appropriate)
✓	US-5,935,159	08/10/1999	Cross Jr., T. E., et al.	607	116	12/15/1997
✓	US-6,249,708	06/19/2001	Nelson, Randy S., et al.	607	122	08/26/1997

FOREIGN PATENT DOCUMENTS

Examiner Initial *	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	I ²
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OTHER DOCUMENTS - NON PATENT LITERATURE DOCUMENTS

Examiner Initial *	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	I ²
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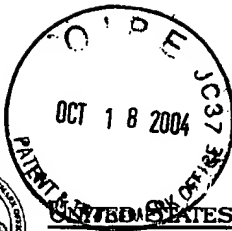
EXAMINER

DATE CONSIDERED

8/16/3

Substitute Disclosure Statement Form (PTO-1449)

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached



A00424

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,000	08/01/2000	Bruce Tockman	279.246US1	8111

21186 7590 08/18/2003

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 08/18/2003



Please find below and/or attached an Office communication concerning this application or proceeding.

PORTFOLIO I.P.
AUG 21 2003
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Office Action Summary	Application No. 09/630,000	Applicant(s) TUCKMAN ET AL.	
	Examiner George R Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-46 is/are pending in the application.
- 4a) Of the above claim(s) 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-26 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/03 has been entered.

Election/Restrictions

Claims 27-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 5.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "coradial" is not used in the specification.

Claim Rejections - 35 USC § 112

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter not described in the original specification is the lead body including two or more "coradial" conductors, wherein the coradial conductors are wound about a

single axis, in combination with the other elements in the claims. The original specification only states that the conductors are "each wound together". Conductors may be wound together, but not have the same radius or axis. Nothing in the specification relates to the conductors being "coradial". This rejection is related to new matter.

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described is the lead body including two or more "coradial" conductors, wherein the coradial conductors are wound about a single axis, in combination with the other elements in the claims. This rejection is related to enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-26 and 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the term "coradial" is vague. It is unclear what "coradial" means since it is not defined or used in the specification and since it can not be found in a dictionary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3762

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-20, 24, 26, 43, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelsson et al (6249708).

Nelson discloses the claimed invention and the use of different types of conductors, (multifilar, unifilar, any combination of the two, DBS) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, it is inherent that the different conductors will have different electrical properties.

Claims 21-23, 25, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.

Nelson discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors having a heat setting capability (claim 25), and the first conductor disposed only in the second and third sections (claims 23 and 44). It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson with the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors and the termination of the first conductor at its respective electrode and connector as taught by Nelson in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead and provide the needed length of the first conductor to provide electrical therapy or sensing to the electrode.

Therefore, it would have been an obvious matter of design choice to modify Nelson to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat

setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration.

Claims 16-20, 24, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr. et al (5935159).

Cross discloses the claimed invention and the use of different types of conductors, (stranded, coiled, having different diameters) individually insulated and wound except for the different conductors being different materials, wherein the first material has a different stiffness than a second material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials, wherein the first material has a different stiffness than a second material since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide different and required impedance/resistances, different current carrying capabilities, and/or different flexibility/stiffness to the lead. In addition, the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section. Also, it is inherent that the different conductors will have different electrical properties and that the con.

Claims 21-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross, Jr et al.

Cross discloses the claimed invention but does not disclose expressly the first material being MP35N and the second material being Pt/Ta (claims 21 and 22), one of the conductors

having a heat setting capability (claim 25), and the lead having a two or three dimensional bias. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Cross with the first material being MP35N and the second material being Pt/TA, because Applicant has not disclosed that the first material being MP35N and the second material being Pt/TA and the first conductor disposed only in the second and third sections provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any two different materials having different stiffness for the conductors as taught by Cross in view of one having ordinary skill in the art, because it would provide a lead having different conductors with different stiffness to provide required current carrying capabilities and/or different flexibility/stiffness to the lead.

Therefore, it would have been an obvious matter of design choice to modify Cross to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities and the lead having a two or three dimensional bias since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration and since it was known in the art that leads are provided with a two or three dimensional bias to allow the lead to be easily located in a particular part of the body and allow the lead to remain in that location.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. In addition, the arguments that "the meaning of 'coradial' is apparent from the specification" for the 112 first paragraph rejection and that "coradial" is reasonably ascertainable from the specification for the 112 second paragraph rejection and lack of antecedent basis for claim terminology are not persuasive since the figures show and the specification describes only the conductors being wound together, and it can not be determined if they are "coradial". US patents 6253111, 4640983, and 6400992, are three teachings of many that show the use of different conductors having different stiffness used in medical leads.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

GRE
August 10, 2003

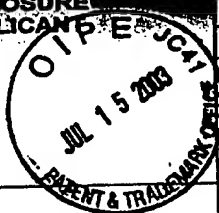
GEORGE R. EVANISKO
PRIMARY EXAMINER

8/10/03

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(Use as many sheets as necessary)



Application Number: 09/630000

Filing Date: August 1, 2000

First Named Inventor: Tockman, Bruce

Group Art Unit: 3762

Examiner Name: Khan, Omar

Attorney Docket No: 279.246US1

Sheet 1 of 1

US PATENT DOCUMENTS

Examiner Initials*	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date if Appropriate
^	US-5,935,159	08/10/1999	Cross Jr., T. E., et al.	607	116	12/15/1997
^	US-6,249,708	06/19/2001	Nelson, Randy S., et al.	607	122	08/26/1997

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
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OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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DATE CONSIDERED

E 9/16/3

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

Notice of References Cited	Application/Control No. 09/630,000	Applicant(s)/Patent Under Reexamination TOCKMAN ET AL.	
	Examiner George R Evanisko	Art Unit 3762	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,400,992	06-2002	Borgersen et al.	607/122
	B	US-			
	C	US-6,253,111	06-2001	Carner, David J.	607/122
	D	US-4,640,983	02-1987	Comte, Pierre-Andre	174/119R
X	E	US-6,249,708	06-2001	Nelson et al.	607/122
X	F	US-5,935,159	08-1999	Cross et al.	607/116
	G	US-			
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	I	US-			
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	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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